

Application No.: 10/008,773  
Amendment Dated: March 14, 2006  
Reply to Office Action of: September 14, 2005

## REMARKS

### 1. Status of Claims

Claims 1-12, 14-48, 50-83 and 85-88 are currently pending in this application. By this Amendment, claims 13, 49 and 84 are canceled, claims 1-3, 5, 9-12, 15, 17-24, 26, 28, 30, 34-36, 38, 39, 41, 42, 45-48, 51, 54, 57, 60, 62, 67-70, 72, 73, 76, 77, 79 and 81 are amended, and new claims 89-91 are added.

### 2. 35 U.S.C. §102(e)

#### (a) Cross, Jr. et al (US6,587,733)

Claims 1-5, 7, 8, 10-14, 17-22, 26-30, 32, 33, 35, 38-41, 43, 44, 46-50, 54-58, 60-69, 72-76, 78 and 80-86 were rejected under 35 U.S.C. §102(e) as being anticipated by Cross, Jr. et al (US6,587,733). Claims 13, 49 and 84 have been canceled without prejudice or admission.

The present application describes, in the last two sentences of paragraph 54, an alternative embodiment in which the insulting member is applied directly to the lead body, for example, by coating. In contrast, exemplary "sleeve-like" embodiments shown or described in the present application include a separate sleeve-like member that may be assembled with a lead body. Other than claim 49 (which has been canceled), the independent claims identified in the previous paragraph (claims 1, 3, 17, 18, 26, 28, 35, 38, 39, 47, 48, 54, 57, 60, 62, 67, 72 and 73) have each been amended to specify either the insulting member or insulating means as being "sleeve-like." Claim 13, which was dependent on claim 1 and was directed to an insulating member that is coated onto the lead body, has been canceled without prejudice or admission.

Cross, Jr. et al '733 discloses among other things a percutaneous surgical lead body with directed stimulation. The Cross, Jr. '733 patent includes the following discussion (column 4, lines 42-59) relating to a non-conductive coating 18 (also shown in figures 4, 5 and 7):

"The medical lead 10 of the present invention defines two sides. As exemplified in FIG. 4, applied to either of the sides is a non-conductive coating 18, preferably a polyurethane, parylene, or similar type coating or paint. The non-conductive coating applied to a portion of the medical lead 10, and specifically the electrode, renders that surface non-conductive. This has the effect of directing the stimulation signal toward the conductive side--the side opposite the coated side--for focused stimulation. Significantly, by coating one side of the medical lead 10 to focus the electrical signal, the lead functions in a manner similar to the surgical paddle-type lead where the electrical signal is transmitted in only one direction. It should be understood that depending on the desired

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stimulation, the amount of coating and the electrode area covered by the coating may vary, as exemplified in FIG. 7. In operation, the medical lead 10 is implanted with the non-coated side of the medical lead 10 placed adjacent to the targeted tissue."

Cross, Jr. et al '733 thus describes a coating but not an electrically insulating sleeve-like member. Accordingly, independent claims 1, 3, 17, 18, 26, 28, 35, 38, 39, 47, 48, 54, 57, 60, 62, 67, 72 and 73 are submitted as not being anticipated, nor rendered obvious, by the Cross, Jr. et al '733 patent, and the claims dependent upon any of the foregoing are also submitted as not being anticipated by Cross, Jr. '733.

The dependent claims are also submitted as further patentably distinguishable over the Cross, Jr. '733 patent.

With respect to claims 3, 4, 18, 19, 28, 39, 40, 62, 63, 74 and 75, which define the second (exposed) portion of the circumference of the lead as extending either approximately 120 degrees or between approximately 110-130 degrees, Cross, Jr. '733 appears to show the portion of electrode as being at some angle not less than 270 degrees in figure 5 and at some angle not greater than 90 degrees in figure 7.

With respect to claims 8, 22, 33, 44, 66 and 78, which specify windows at different circumferential positions about the lead body, please note for example figures 5-8, which illustrate exemplary embodiments in which different windows are provided at different circumferential positions. This feature is also not shown in Cross, Jr. et al '733. The claimed different circumferential positions facilitate providing directional stimulation in various directions with a single lead.

With respect to claims 11, 47, 68 and 82, which specify the sleeve-like member as being molded to define the window, Cross, Jr. et al '733 describes a coating and not a sleeve-like member that is molded to define a window.

With respect to claims 12, 48, 69 and 83, which describe the sleeve-like member as being cut to define the window, Cross, Jr. et al '733 does not describe making such a cut.

**(b) Lagergren (US3,911,928)**

Claim 9, 23, 31, 34, 42, 45, 53, 59, 77, 79 and 87 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lagergren (US3,911,928). Independent claims 9, 23, 34 and 45 have been amended to specify the insulting member or insulating means as being "sleeve-like."

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The Office Action characterizes Lagergren '928 as disclosing "a plurality of electrodes 5 and a window 4 that is pitched to extend in a spiral pattern along the length and about the circumference of the insulating member." Lagergren '928 describes element 4 as being electrically insulating material that is part of the electrode head construction as follows (column 3, lines 9-18):

"The surface of the electrode head 3 is partly constructed of an electrically insulating material 4 which is not irritative to the body, and partly of an electrically conductive contact material 5. In the embodiments of FIGS. 1 and 2, the contact material 5, which lies on the surface of the electrode head, is band-shaped. Thus, in the construction of FIG. 1, the band-shaped contact material extends in mutually parallel lengths or strips along in the axial direction of the cylindrically shaped electrode head."

Lagergren '928 thus does not describe a sleeve-like insulating member or sleeve-like insulating means, much less such a member or means having a window or window means that exposes a portion of an electrode while other portions of the electrode are covered by the insulating member or means. Accordingly, independent claims 9, 23, 34 and 45 are submitted as not being anticipated by Lagergren '928, and the claims dependent upon any of the foregoing are also submitted as not being anticipated, nor rendered obvious, by Lagergren '928.

### 3. 35 U.S.C. §103 (Lagergren '928)

Claims 15, 16, 24, 25, 36, 37, 51, 52, 70, 71 and 88 stand rejected under 35 U.S.C. §103(a) as being unpatentable (obvious) over Lagergren (US3,911,928). Independent claims 15, 24, 36, 51 and 70 have been amended to specify the insulating member or insulating means as being "sleeve-like." These claims are believed to be patentable for at least the reasons discussed above in Section 2(b) of these remarks with respect to the 35 U.S.C. §102(b) rejections over Lagergren '928.

### 4. New Claims

New independent claim 89 is directed to the feature of a plurality of windows being provided in the insulating member with at least two windows being defined at different circumferential positions about the lead body. See, for example, figures 5-8 for an illustration of two illustrative embodiments having this feature. This feature is simply not shown or suggested

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in the Cross, Jr. '733 patent or Lagergren '928 patent. Accordingly, the allowance of claims 89-91 is requested.

**5. Extension of Time, Authorization to Charge Fees**

The transmittal letter attached to this response includes a request for a three month extension of time to respond to the Office Action, as well as authorization to charge any fees to Deposit Account 13-2546 in connection with such extension, the amended or new claims, or otherwise in connection with this paper.

In view of the foregoing amendments, reconsideration and allowance of this application are requested.

Respectfully submitted,



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Stephen W. Bauer  
Registration No. 32,192  
MEDTRONIC, INC.  
710 Medtronic Parkway NE, M.S.: LC340  
Minneapolis, Minnesota 55432-5604  
Telephone: (763) 505-0422  
Facsimile: (763) 505-0411  
**CUSTOMER NO.: 27581**